INFORMED CONSENT FOR THE SECONDARY RESEARCH USE OF RESIDUAL NEWBORN SCREENING DREID BLOOD SAMPLES

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- Interpretations are our own. Do not necessarily reflect views of APHL or CDC.
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Part I

- Requirements of legally valid informed consent

§46.116 General requirements for informed consent.

- Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(a) Basic elements of informed consent. (emphasis added)

Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

Informed Consent Req'ts Cont'd.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;(N/A)

Informed Consent Req’ts Cont’d.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent.

- When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (N/A?)
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; (N/A)
- (3) Any additional costs to the subject that may result from participation in the research; (N/A)
- (4) **The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;**
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and (N/A)
- (6) The approximate number of subjects involved in the study. (N/A)

Waiver or Alteration of Consent

- Provisions related to waiver or alteration of informed consent requirements DO NOT APPLY pursuant to the new law

- Questions?

Part II

- Draft Informed Consent Document

Draft Informed Consent Document

- SACHRP recommends that OHRP consider developing an example document for broad consent to research use of newborn dried blood spots as part of its guidance.
- SACHRP encourages OHRP to evaluate these state models and see if they might be useful at the national level.
- Draft Development Process: Reviewed consent documents (proposed in Minnesota) for secondary use of DBS from Massachusetts,* Michigan, Minnesota & Texas
- Our analysis of whether consent documents fulfill Common Rule criteria
- Developed DRAFT informed consent document for discussion purposes

DRAFT INFORMED CONSENT DOCUMENT FOR RETENTION AND USE FOR SECONDARY RESEARCH OF RESIDUAL NEWBORN SCREENING DBS

- INTENDED FOR ILLUSTRATIVE PURPOSES ONLY
- THIS DOCUMENT HAS NOT BEEN REVIEWED BY OHRP AND MAY NOT SATISFY CRITERIA FOR LEGALLY INFORMED CONSENT UNDER THE COMMON RULE.
- THIS DOCUMENT IS NOT INTENDED AS LEGAL ADVICE. PLEASE SEE YOUR STATE'S LEGAL COUNSEL FOR ADVICE ABOUT THIS TOPIC IN YOUR STATE.

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Informed Consent Content

What do I need to know about newborn screening dried blood spots? After newborn screening is completed, some of your baby's dried blood may be left over. Under state law, your baby's left over dried blood sample must be kept by the state for X period time. During that time, the Department of Health can use this leftover blood to help make sure that the newborn screening tests and equipment are working properly.

Informed Consent Content

How can dried blood spots be used for research? If you say, "Yes,", your baby's leftover blood also could be used for important medical research. If you say, "Yes," your baby's leftover blood could be used for research on cancer, birth defects, infectious disease, chronic disease, environmental exposures, newborn screening or other types of important biomedical or public health research. Your baby's blood will NOT be used for any research related to cloning people.

- (NOTE: UNCLEAR AT THIS TIME WHAT LEVEL OF SPECIFICTY WILL BE REQUIRED TO MEET REQUIREMENTS OF LEGALLY VALID INFORMED CONSENT)
- (Study involves research)

Informed Consent Content

How long will the state keep my baby's dried blood spot? If you say, "Yes," your baby's blood spot will be kept by the state and can be used for important medical research for up to X years.

Informed Consent Content

What are the risks if my baby's blood spots are used for research? The only risk to you or your baby is that your baby's blood spot could be identified. The risk that this would happen is very low. Many steps are taken to protect your child's privacy.

- (MAY NEED TO INCLUDE SPECIFIC STEPS STATE TAKES TO MAINTAIN PRIVACY).
- (Foreseeable risks)

Informed Consent Content

Will I or my baby benefit from blood spot research?

If you allow your baby's dried blood spot to be used for important research, you or your baby likely will not benefit directly. You will not be paid if your baby's blood spot is used for research, but your family and other families may be helped in the future by research that helps to find new ways to diagnose, prevent, or treat disease.

- (Benefits)

Informed Consent Content

What are the steps for using blood spots in research?

1. A researcher who would like to use dried blood spots for research must submit an application to the state Department of Health.
2. The state Department of Health Institutional Review Board must review the application to make sure that the baby's rights are protected. An Institutional Review Board is a special committee created to make sure that research is conducted in an ethical manner that protects research subjects.
3. Any information that could be used by the researcher to identify your baby is removed from the sample. No information that could be used to identify any single person would be given to a researcher without that person's permission.

Informed Consent Content

What steps are taken to protect privacy? (NEED TO DESCRIBE STEPS TAKEN IN STATE TO PROTECT PRIVACY AND SECURITY OF SAMPLE)

- (Confidentiality of records)

Informed Consent Content

Can I change my mind about blood spot research? Yes. You can call the Department of Health at any time if you do not want your child's blood spot used for research. Your child may contact the Department after he or she turns 18 if he or she does not want the dried blood sample to be used for research.

- (THIS LANGUAGE MAY NOT BE CORRECT FOR EVERY STATE. THE IMPORTANT POINT IS TO NOTE THAT PARENTS AND CHILDREN WHEN THEY TURN 18 CAN CHANGE THEIR MIND AND NEED TO STATE WHAT HAPPENS IF THEY CHANGE THEIR MIND.)
- (Consequences of subject's decision to withdraw)
- (May discontinue participation at any time)

Informed Consent Content

What happens if I say, "No?" Your baby's blood will still have newborn screening done as required by state law. Allowing your child's dried blood spot to be used for research is completely voluntary. If you say, "No," the care your baby receives will not be affected in any way.

- (Alternatives)
- (No penalty/Participation is voluntary)

Informed Consent Content

Who should I contact if I have questions or believe that I have been harmed? If you have questions about the possibility of having your child's dried blood sample be used for research or believe that you may have been harmed by allowing your child's dried blood sample to be used for research, please contact the Department of Health at:

DOH Address

Phone number

- (Whom to contact if questions)

Part III

- Issues related to documentation of informed consent

§46.117 Documentation of informed consent.

- (a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Documentation of Consent Req't

- (b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
- (1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- (2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Conditions for Waiver of Documentation of Consent

- (c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Thank you.